REMARKS

In response to the Office Action mailed July 7, 2005, Applicants respectfully request that the Examiner reconsider the above-captioned application in view of the foregoing amendments and the following comments.

Rejection of Claims 1-5, 8, 9, 22, 24, 27-29, 32 and 33 under 35 U.S.C. § 102(e)

The Examiner rejected Claims 1-5, 8, 9, 22, 24, 27-29, 32 and 33 under 35 U.S.C. § 102(e) as being anticipated by Huter et al. (6,511,496). The Examiner alleges that Figure 1 shows a prosthetic valve having an anchor structure on a balloon, which is attached to a catheter device that has a collar 40 proximal to the anchor. The Examiner further alleges that the collar 40 is attached to a cantilever strut assembly 24 having a membrane assembly 22 attached thereto.

The Applicants respectfully assert that the Examiner has mischaracterized the structure cited in Huter et al., and that Huter et al. does not disclose all the elements claimed in Applicants' independent Claim 1.

Huter et al. Does Not Disclose a Valve with a Closed End

Claims 1, 32 and 33 of the present application disclose and claim a valve having a biocompatible membrane assembly. The membrane assembly has a substantially tubular configuration about the longitudinal axis, with first open and a second closed end. In the closed position, the valve is configured to substantially prohibit retrograde blood flow to pass through the valve.

Conversely, Huter discloses an embolic protection device or filter for capturing embolic particles entrained in blood flowing in an arterial vessel during interventional procedures. The

filter includes an expandable strut assembly and a filtering medium. The filtering medium is formed from a thin elastic polymer membrane containing a plurality of holes, which allow blood to pass through the filter while capturing embolic particles. If the filtering medium did not allow blood to pass through it, it would not be able to filter embolic particles. See Abstract generally.

Huter Does Not Have an Anchor Structure Having First and Second Open Ends Attached to the Connecting Member

Claims 1, 32 and 33 of the present application describe and claim an expandable structure, including an anchor structure having first and second open ends, and at least one connecting member. Claims 32 and 33 require the anchor structure to be formed from a lattice of interconnected elements. The first end of the connecting member is attached to the second end of the anchor structure. Claims 1 and 32 further claim that the second end of the connecting member is cooperatively associated with one end of a cantilever valve strut. Claim 33 claims a connecting member where the second end of the connecting member is attached to collar located.

The Examiner alleges that Huter discloses an anchor structure on a balloon, which is attached to a catheter device. However, the Examiner has not clearly pointed out what member in Figure 1 represents the anchor structure, and there is nothing in Huter disclosing an anchor structure on the balloon. Figure 1 depicts an angioplasty balloon back loaded over a guidewire. There is some kind of geometric shape on the balloon (represented but not identified in the figure), but is not described in the specification. The examiner seems to argue that this is an anchor structure having first and second open ends as recited in Applicants' Claim 1. However, the Applicants respectfully assert that this could just as easily be ribbing or a textured surface on the balloon outer surface to prevent slipping across the lesion. The specification does describe a

stent, which could arguably be construed as an anchor structure, but the specification states that once the balloon angioplasty procedure is complete, the balloon catheter 28 is removed and may be followed by a stent-delivery catheter (not shown) for placement of a stent across the dilated lesion. See col. 5, lines 57-61. This implies that dilation balloon does not have a stent over its outer surface. In addition, the specification specifically states that the stent-delivery catheter is not shown, intimating that the stent is not shown in the figures.

Assuming, *arguendo*, that Figure 1 does shown a stent over the dilation balloon, the stent could not be an anchor structure attached to the connecting members. It is clear from Figure 1 that the alleged stent is not attached to strut assembly 24, which is a limitation in the Claim 1, but is instead a free standing structure.

In addition, the balloon 30 in Huter is not an anchor structure and is not attached to a connecting member. Instead the balloon 30 in Huter is used to perform an angioplasty procedure and radially expanding or dilate artherosclerotic plaque. See col. 5, lines 45-57. The balloon 30 is attached to a balloon dilatation catheter 28 that is advanced over a guidewire. See col. 5, lines 45-55. The filter device containing the strut assembly 24 is rotatably mounted on the distal end of the guidewire. See col. 5, lines 37-38. Because the balloon catheter 28 is back loaded and advanced over the guidewire, the balloon 30 cannot be attached to any component of the filter device. It is clear that the balloon assembly and filter device assembly are two complete and unattached devices.

In addition, the balloon does not have first and second open ends.

Huter Does Not Disclose a Connecting Member

As described above, Claims 1, 32 and 33 claim an expandable structure, including an anchor structure having first and second open ends, and at least one connecting member. The first end of the connecting member is attached to the second end of the anchor structure. Claim 33 further claims a collar located proximal to the radially expandable anchor, and a connecting member attached between the second of the anchor and the proximal collar.

The Examiner does not describe any component in Huter being a connecting member as claimed in independent Claim 1. The Examiner only describes a collar 40 in Huter, and alleges that collar 40 is attached to the catheter device, and the catheter device is attached to the balloon.

The strut assembly 24 of the filter device 20 includes an elongated cylindrical center portion 34 and proximal and distal end portions 36 and 38, terminating at proximal and distal, hollow, cylindrical guide wire collars 40 and 42. See col. 6, lines 7-12. Figure 3 clearly shows that the collar 40 is part of the strut assembly. As described above, the filter device containing the strut assembly 24 is rotatably secured to the distal end of the guidewire. See col. 5, lines 37-38. See also col. 8, lines 50-62. The balloon 30 is attached to the balloon dilatation catheter 28 that is advanced over the guidewire. See col. 5, lines 45-55. Because the balloon catheter 28 is back loaded and advanced over the guidewire (which is attached to the collar 40), the balloon 30 cannot be attached to any component of the filter device, including collar 40. Accordingly, Huter does not disclose a connecting member being attached to the second end of the anchor structure.

Huter Does Not Disclose Cantilever Valve Struts

Claims 1, 32 and 33 of the present application claim a cantilever valve strut having first and second ends, where the first end of the cantilever valve strut is cooperatively associated with the second end of the connecting member. The Examiner alleges that the cantilever valve strut assembly is expandable strut assembly 24.

The Applicants assert that the strut assembly 24 is not a cantilever valve strut. Instead, the strut assembly 24 in Huter is made up of individual struts 44. It is these struts 44 that are more appropriately akin to the cantilever valve struts claimed in the present application. However, it is clear from Figure 3 that the struts 44 in Huter are not cantilever valve struts as claimed by Applicants. Instead the struts 44 in Huter are fixed at both ends to collars 40 and 42. Even assuming that strut assembly 24 may be construed as a structurally equivalent member to the cantilever valve strut in Claims 1, 32 and 33, the strut assembly 24 is also not a cantilevered member.

A cantilever member is fixed on one end, having a second end that is free to deflect and move. The first end of the strut assembly 24 in Huter is attached to collar 40, but the second end is not free to deflect. Indeed the guidewire is slid through the second end of the strut assembly 24, restraining the second end and only allowing longitudinal movement of the strut assembly 24 relative to the guidewire. This arrangement is more akin to a beam fixed on one end by a pin, while the second end is allowed to slide on a roller, which is not considered a cantilevered member.

Because Huter et al fails to disclose each of the elements recited by independent Claims 1, 32 and 33, Huter cannot anticipate Applicants' claimed device under 35 U.S.C. §102(b).

Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of Claim 1, 32 and 33 under 35 U.S.C. § 102(b) as being anticipated by Huter. As Claims 2-22, 24, and 27-29 depend directly or indirectly from independent Claim 1, Applicants similarly request that the Examiner withdraw the rejection to these claims under 35 U.S.C. § 102(b) as being anticipated by Huter. Further, Applicants assert that Claim 1 is an allowable generic claim linking Claims 23, 25, 26, 30 and 31. Accordingly, Applicants respectfully request the Examiner reinstate and allow these claims.

Rejection of Claim 11 under 35 U.S.C. § 103(a)

The Examiner rejected Claim11 under 35 U.S.C. § 103(a) as being unpatentable over Huter et al, in view of Konya et al. (6,368,338). The Examiner admits that Huter fails to disclose that the membrane material comprises a reinforcement fiber, but that Konya teaches that the filtering device can include reinforcement of structural fibers.

Konya does not Teach a Membrane Having Reinforcement Structural Fibers

The Applicants respectfully assert that the Examiner has mischaracterized the structure cited in Konya, and that Konya does not disclose a valve device, a filter device or a fiber reinforced membrane.

Konya discloses an occlusion device for occluding a vessel. The occlusion device comprises elastically deformable members 12 and a jacket 16. In the specification section cited by the examiner (col. 12, lines 23-31), polyester threads are used as an occluding agent 20 to facilitate quicker occlusion by providing more sites for thrombosis to occur. See also Figure 11.

The polyester threads are not reinforcement fibers, and particularly not reinforcement fibers contained in a synthetic membrane used as a valve.

Conversely, the present invention clearly describes and claims a valve membrane having reinforcement fibers to further support the membrane.

Accordingly, Huter and Konya individually or in combination do not include all the Claim limitation in independent Claim 1. As a result, Huter in view of Konya fails to teach all the claim limitations of dependent Claim 11. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claim 11 under 35 U.S.C. § 103(a).

There is no Teaching or Suggestion to Combine the References

A rejection under 35 U.S.C. § 103(a) requires that the Examiner make a factual showing that the claimed subject matter, as a whole, would have been obvious to a person of ordinary skill in the art. The combination of two or more references is only proper if there is some objective teaching in the prior art that would lead one of ordinary skill to combine the relevant references. The references must be taken in their entireties. It is impermissible within the framework of 35 U.S.C. § 103 to pick and choose from a reference only so much of it as will support a conclusion of obviousness. Accordingly, it is the Examiner's affirmative duty to show such a teaching in the art.

The Applicants respectfully assert that the Examiner has not met his burden under 35 U.S.C. § 103(a). The Examiner merely states that Konya teaches that the filtering device can include reinforcement or structural fibers, and that it would have been obvious to use reinforcement fibers as taught by Konya with the membrane of Huter such that is strengthens the apparatus and prevents collapse. The Examiner has not made an affirmative showing that the two references

should be combined.

Huter discloses an embolic protection device or filter for capturing embolic particles entrained in blood flowing in an arterial vessel during interventional procedures. The filter includes an expandable strut assembly and a filtering medium. The filtering medium is formed from a thin elastic polymer membrane containing a plurality of holes that allow blood to pass through the filter while capturing embolic particles. See Abstract generally. Konya teaches an occlusion method and apparatus for creating a thrombus in a vessel for occlusion of the vessel. The devices each serve completely different functions, are different devices, and do not teach or suggest any combination of the two devices.

Applicants assert that Huter is not properly combinable with Konya for a rejection under 35 U.S.C. § 103(a). Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claims 1-5 and 7-10 under 35 U.S.C. § 103(a).

Rejection of Claims 6 and 7 under 35 U.S.C. § 103(a)

The Examiner rejects Claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Huter et al. in view of Quijano et al. (5,500,014). The Examiner asserts that Huter meets the claim limitations of Claim 1, but does not disclose that the use of biological vein material for the membrane.

As discussed above, the cited structure in Huter does not include all the Claim limitation in independent Claim 1. As a result, Huter in view of Quijano fails to teach all the claim limitations of dependent Claims 6 and 7. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claims 6 and 7 under 35 U.S.C. § 103(a).

Rejection of Claims 10, and 12-21 under 35 U.S.C. § 103(a)

The Examiner rejects Claims 10 and 12-21 under 35 U.S.C. 103(a) as being unpatentable over Huter et al. in view of Alt et al. (5,788,979). The Examiner asserts that Huter meets the claim limitations of Claim 1, but does not disclose that the structural frame or membrane is covered with a therapeutic agent. However, the Examiner asserts that Alt teaches that biodegradable polymer materials can be loaded with drugs or pharmaceutical agents.

As discussed above, the cited structure in Huter does not include all the Claim limitation in independent Claim 1. As a result, Huter in view of Alt fails to teach all the claim limitations of dependent Claims 10 and 12-21. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection of Claims 10 and 12-21 under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing amendment and remarks, Applicants respectfully assert that the present application is now fully in condition for allowance, and such action is respectfully requested. If any issues remain that may be addressed by a phone conversation, the Examiner is invited to contact the undersigned at the phone number listed below.

A Petition for a 1 Month Extension of Time, along with authorization to charge the petition fee to the Applicant's Deposit Account, are being submitted with this Amendment and Response. No additional fee is thought to be necessary to enter this Amendment and Response.

If an additional fee is required, the Examiner is authorized to charge the Applicants' Deposit Account - Account Number 10-0750/CRD-5051.

Respectfully submitted,

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